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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,173	03/01/2004	Fred H. Burbank	R0367-00103	1003

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EXAMINER

TOWA, RENE T

ART UNIT PAPER NUMBER

3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODÉ
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/790,173	Applicant(s) BURBANK ET AL.	
	Examiner Rene Towa	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,40-45 and 47-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,40-45 and 47-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/05/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to the amendments filed December 8, 2006. Claims 1, 40-45 and 47-53 are pending. No claim has been added. Claims 1, 40-45 and 47-53 have been amended. Claims 46 and 54-56 have been cancelled.

Claim Objections

2. The objection is withdrawn due to amendments.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1, 40-43, and 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis (US Patent No. 5,794,626) in view of Tihon et al. (US Patent No. 5,415,656).

In regards to claim 1, Kieturakis discloses a biopsy instrument 5 for retrieving body tissue, comprising:

an elongated shaft 40 having a longitudinal axis and distal end 45 adapted for entry into a patient's body by penetrating tissue; and

a cutting element 15 disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position and which is rotationally movable in said radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen; and

an outer sheath slidably disposed about the shaft and configured for axial movement between distal and proximal positions for selectively covering and uncovering the cutting element (see figs. 1-3; column 3/lines 61-67; column 6/lines 13-19; column 9/lines 11-17).

In regards to claim 42, Kieturakis discloses a biopsy instrument wherein the cutting element 15 has a proximal end 23 and a distal end 24 and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended position (see fig. 2).

In regards to claim 43, Kieturakis discloses a biopsy instrument wherein the cutting element 15 is configured so that the distal end 24 is fixed and the proximal end 23 moves toward the distal end 24 in order to radial extend the cutting element 15 (see figs. 2-3).

In regards to claim 47, Kieturakis discloses a biopsy instrument including a proximal driver unit 150 for controlling radial expansion and retraction of the cutting element and rotation of the cutting element about the longitudinal axis (see column 6/lines 13-19, 44-52, 56-62 & 66-67; column 7/lines 1-4 & 31-36; column 8/lines 2-10).

In regards to claim 48, Kieturakis discloses a biopsy instrument wherein the proximal driver unit 150 further controls axial movement of said shaft 40 (see column 6/lines 13-19, 44-52, 56-62 & 66-67; column 7/lines 1-4 & 31-36; column 9/lines 11-17).

In regards to claim 49, Kieturakis discloses a biopsy instrument wherein the cutting element 15 is configured to be manipulated to segment the tissue specimen (see figs. 2-3; column 3/lines 61-67).

In regards to claim 50, Kieturakis discloses a biopsy instrument wherein the electrosurgical proximal tissue cutting element 15 is configured to segment the tissue specimen after it has been isolated from the surrounding tissue (see figs. 2-3; column 3/lines 61-67).

In regards to claim 51, Kieturakis discloses a biopsy instrument wherein the tissue cutting element 15 is capable of segmenting the tissue specimen as it is being retracted from said radially extended position to said radially retracted position (see figs. 2-3).

In regards to claim 52, Kieturakis discloses a biopsy instrument wherein the radially extended position comprises a first radially extended position, and wherein the cutting element 15 is further actuatable to a plurality of additional radially extended positions and rotatable about the longitudinal axis in each of said radially extended positions to selectively peripherally segment said tissue specimen (see figs. 2-3).

In regards to claim 53, Kieturakis discloses a biopsy instrument wherein the instrument further comprises a cannula 10 having a lumen 56 for providing a passageway into the patient's body, the segments of the tissue specimen being removable from the patient's body through the cannula 10 (see fig. 3).

Kieturakis discloses a system, as described above, that teaches all the limitations of the claims except Kieturakis does not teach an electrosurgical cutting step.

However, Tihon et al. disclose an apparatus comprising an electrosurgical cutting wire 1, energized by radio frequency (RF) energy; wherein an electrical conductor 35 having a distal end electrically connected to the electrosurgical cutting element and a

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proximal end configured to be connected to a source ESU to deliver radio frequency energy from the source to the electrosurgical cutting element (see figs. 2 & 8; column 1/lines 65-68; column 2/lines 1-5 & 20-31; column 3/lines 21-33; column 5/lines 56-64; column 8/lines 32-41).

As such, further in regards to claims 1 & 40-41, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kieturakis with an electrosurgical cutting step similar to that of Tihon et al. in order to make the cutting operation easier, more direct and thus less traumatic, than cutting with an unpowered cutter. Moreover, use of RF powered cutting element permits the convenient application of coagulating power for hemostasis (see Tihon et al., column 1/line 65 to column 2/line 5).

Moreover, in regards to claim 48, since Kieturakis discloses a power unit and an outer sheath that is slidably disposed about the shaft (see column 6/lines 13-19, 44-52, 56-62 & 66-67; column 7/lines 1-4 & 31-36; column 9/lines 11-17), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kieturakis as modified by Tihon et al. with a power unit that controls movements of the sheath since such a modification would amount to a design choice. It has previously been held that merely making automatic is not patentable--See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 192, 194 (CCPA 1958).

5. Claims 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis ('626) in view of Tihon et al. ('656) further in view of Treat (US Patent No. 4,493,320).

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Kieturakis as modified by Tihon et al. discloses a system, as described above, that teaches all the limitations of the claim except Kieturakis as modified by Tihon et al. does not explicitly teach a bipolar or monopolar electrode.

However, Treat discloses a system comprising a bipolar electrode 24 (see fig. 3; column 3/lines 14-19; column 4/lines 44-49).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kieturakis as modified by Tihon et al. with a bipolar electrode similar to that of Treat in order to localize the cauterization to a small predefined volume of tissue (see Treat, column 2/lines 31-41).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kieturakis as modified by Tihon et al. with a monopolar electrode in order to provide to cauterize an undefined volume of tissue.

Response to Arguments

6. Applicant's arguments filed December 8, 2006 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RTT

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